

The VacScene

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The VacScene is a publication of Public Health – Seattle & King County written for health professionals. Content is consistent with the most current recommendations from the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP).

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Influenza Vaccine Recommendations and Updates for the 2007-2008 Flu Season

Public Health-Seattle and King County's VFC Program has received 98% of the state-supplied allocation of influenza vaccine. Vaccine continues to be shipped to VFC providers as individual clinic need and storage capacity allows.

Primary Updates and Key Messages in the 2007 Recommendations from the Centers for Disease Control and Prevention (CDC):

- The importance of administering 2 doses of vaccine, separated by >4 weeks, to all children aged 6 months--8 years if they have not been vaccinated previously at any time with either the intranasal spray or injectable vaccine. If the child fails to get the second dose during that season, he should be given two doses in the next influenza vaccination season. If he fails to receive those two doses, he should only get one dose per year from that point on.
- All persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others should be vaccinated.
- Vaccinate health care workers. Health care workers can transmit influenza virus to both patients at higher risk for complications from influenza and co-workers .
- Offer influenza vaccine and schedule immunization clinics throughout the influenza season. Since 1976, approximately 80% of the time peak influenza activity has not occurred until January or later and typically peaks locally in February.

Injectable Trivalent Influenza Vaccine (TIV) and intranasal Live-Attenuated Influenza Vaccine (LAIV, or "FluMist"). Both vaccine formulations include protection against A/Solomon Island/3/2006 (H1N1)-like, A/Wisconsin/67/2005 (H3N2)-like and B/Malaysia/2506/2004-like antigens.

FluMist Updates:

- Newly licensed age range: As of September 19, 2007, FluMist was licensed for use in healthy persons 2 to 49 years of age. Previously, this vaccine could be given only to individuals ages 5 to 49. (Note: FluMist is not available through WA State's Vaccines For Children (VFC) program at this time).
- The new formulation of LAIV can now be stored in the refrigerator at 35F-46F. It no longer should be stored in the freezer.
- The new formulation is supplied in a pre-filled, single use sprayer containing 0.2mL (compared to the previous dosage of 0.50 mL). Approximately 0.1 mL is sprayed into each nostril while the recipient is in the upright position.

To read the full text of ACIP recommendations for the prevention of influenza, visit:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5606a1.htm> MMWR 2007 Jul 13; 56(RR06):1-54.

WA State Law: Restriction Imposed on Use of Thimerosal-Containing Flu Vaccine

It has come to our attention that some health care providers may be unaware of the 2006 Washington State law restricting thimerosal content of vaccines administered to children under 3 years of age and pregnant women. The law was passed in April 2006, effective beginning July 2007 and makes it illegal to administer vaccines with thimerosal in excess of the specified limit. The law applies only to certain influenza vaccines and the only available Japanese encephalitis vaccine.

Two documents about the law from WA Department of Health (DOH) that were previously sent to healthcare providers by DOH are available at:

<http://www.doh.wa.gov/cfh/Immunize/documents/parentinfo5305.pdf>

<http://www.doh.wa.gov/cfh/Immunize/documents/providerinfo5305.pdf>

Vaccines For Children (VFC) Program News

Influenza vaccine and the VFC Program – How does it work?

- The CDC determines the quantity of flu vaccine that each state receives each year, and the Washington State Department of Health (DOH) chooses the vaccine presentations (packaging). CDC allocations are based on estimated number of VFC eligible children, expected "uptake," and available funding for purchase of vaccine from manufacturers at the federal contract rate. King County's VFC Program does not have control over the amount or formulations that are made available to us. We receive a set number of doses for children 6 months to through 18 years, and for this reason, VFC providers may see their order adjusted to fit availability. Overall, however, VFC does not anticipate reducing flu vaccine requests.
- Manufacturers ship flu vaccine to the CDC's vaccine distributor, McKesson Specialty, in Memphis, Tennessee. DOH then notifies Public Health when flu vaccine is available at McKesson for King County to distribute. To the extent possible, VFC will ship flu vaccine together with other vaccine orders.
- Manufacturers deliver the total order of flu vaccine in 3-5 partial shipments. VFC fills a proportion of the order for each of our 340 enrolled VFC provider locations in King County as soon as the first lot arrives and we continue distributing as we receive vaccine until orders are completely filled. We fill a proportion of the order for all clinics to assure that vaccine is available as widely as possible throughout the county and, for some sites, to avoid exceeding clinic storage capacity.
- This year in the US, vaccine makers project availability of a record number of doses of flu vaccine, about 130 million over the course of the manufacturing season.
- Large commercial vaccinators, such as WalMart or Costco, are able to hold flu clinics before there is much flu vaccine available at individual practices/clinics because the total volume of vaccine that these businesses order is so large that their initial shipments are proportionally larger than the VFC program orders.
- Late-season flu vaccine is already scheduled to be provided at area grocery and drug stores on November 30th and December 1st. Encourage unvaccinated patients to consider visiting these late-season clinics. You can also direct people to visit www.getaflushot.com for information on general access to flu vaccine.

Vaccine Supply Notification

In order to provide you with information that may impact vaccine ordering and/or usage in your practice, Public Health will attempt to routinely notify VFC Program participants of unanticipated and/or significant vaccine supply problems within 24-48 hours of our becoming aware of the problem. Public Health will use email and broadcast fax to communicate this information to health care providers, as well as *VacScene* articles when appropriate.

Making the right choice: Tdap or Td?

Students entering the 6th grade in the 2007-8 school year may be required to show documentation of a dose of Tdap (VFC Program supplies Boostrix). The school requirement applies **if the student is 11-12 years old and if it has been at least five years** since the last DTaP, DTP, pediatric DT or adult Td. Vaccinating these children with Td (Decavac) will **not** meet the requirement. **IMPORTANT! Schools cannot require a dose of Tdap for 6th-graders if they are not yet 11-12 years of age.**

Pre-teens and adolescents without documentation of having received their primary series of tetanus/diphtheria-containing

vaccines should get started! The preferred schedule is a dose of Tdap, followed by a dose of Td at least four weeks later and a second dose of Td 6-12 months after that. For adolescents who have received a dose of Td, the recommended interval between Td and Tdap is five years, although ACIP did not define an *absolute* minimum interval between DTaP/DT/Td and Tdap. The decision to administer Tdap should be based upon whether the benefit of pertussis protection outweighs the risk of a local adverse reaction (e.g. pain, swelling, redness at the injection site). By protecting our adolescents from pertussis, we are also providing protection for babies who are too young to be immunized or who have not completed their primary series.

Pregnant teens up to the 19th birthday should receive a single dose of Tdap in the immediate post-partum period if they previously have not received Tdap. Young women up to the 19th birthday who might become pregnant are encouraged to receive a single dose of Tdap. (**Note:** Pregnant women 19 years and older are also encouraged to receive Tdap in the post-partum period; please use your *purchased* Tdap vaccine for this population).

Adolescents up to the 19th birthday who require tetanus toxoid-containing vaccine as part of wound prophylaxis should receive Tdap instead of Td **if** they have not previously received Tdap. If Tdap was given previously, give Td. (**Note:** Tdap is also recommended for individuals ages 19 and older who required tetanus toxoid-containing vaccine for wound prophylaxis, however you would need to administer vaccine from your purchased supply for this age group).

Rotavirus Vaccine – Are You Providing This Important Vaccine to Your Patients?

RotaTeq® rotavirus vaccine was licensed for use among US infants in February 2006 and was made available to VFC providers in King County in May 2007. In the US most children are infected with rotavirus by age five years, and while the disease causes relatively few deaths (20-60)¹, illness results in more than 400,000 physician visits, and 55,000-70,000 hospitalizations annually. This translates into approximately 2,400 physician visits and 330-420 hospitalizations among King County children. Annual costs associated with rotavirus disease are estimated at around \$1 billion dollars nationally. However, VFC providers in King County have been slow to order RotaTeq®. The restriction on administration of oral drugs by medical assistants in Washington State is one factor that has limited access of this vaccine for eligible children. However, until that problem is corrected, *Public Health encourages healthcare providers to make an extra effort to find a way to administer rotavirus vaccine in your practice setting.*

A review of the efficacy, safety, administration and dosing for RotaTeq® with a tip on how providers can administer this important vaccine follows:

Efficacy: A three-dose series of RotaTeq® has been shown to prevent 74% of all rotavirus cases and 98% of severe cases.

Safety: An earlier rotavirus vaccine was associated with a rare condition called intussusception, which was not identified during prelicensure trials because too few children were studied. RotaTeq® was evaluated in nearly 70,000 infants, making it one of the largest prelicensure trials in vaccine history. After the FDA notified health care providers and consumers that it had received reports of intussusception, a CDC media relations press release issued on

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March 15, 2007 by both ACIP and CDC concluded **“that the number of intussusception reports after administration of RotaTeq® has not exceeded the number expected to occur without vaccination and that the vaccine does not appear to be associated with intussusception.”**² CDC is also conducting a large study (90,000 infants) that will quickly identify any association between RotaTeq® and intussusception or other adverse events through the Vaccine Safety Data Link (VSD).

Administration: RotaTeq® is an oral vaccine. Each 2 ml dose is supplied in a plastic tube with a twist off cap. The dose is squeezed into the infant's mouth toward the inner cheek. Currently, MAs are not authorized to administer this vaccine in Washington. **Don't let this prevent an infant from receiving this vaccine.** The provider can administer the vaccine as part of the infants' physical exam. It has been suggested that the sweet taste of rotavirus vaccine may provide an analgesic-type effect for subsequent vaccines given by injection during the same visit.

Dosage: The vaccine is recommended at age 2, 4, and 6 months. Do not start the series later than age 12 weeks and the final dose must be administered before 32 weeks, even if fewer than three doses have been administered.

¹ Kilgore PE, Holman RC, Clarke MJ, Glass RI. Trends of diarrheal disease—associated mortality in U.S children, 1968 - 1991. JAMA 1995; 274:1143-8.

² CDC Media Relations. CDC Releases Safety Data on Rotavirus Vaccine Reported Intussusception Cases Fall Within Expected Range. March 15, 2007

New Hepatitis A Vaccine Guidelines for Post-Exposure Prophylaxis and Pre-Travel Use

At their June 27-28, 2007 meeting, the ACIP approved provisional recommendations for the use of **single antigen hepatitis A vaccine** for pre-travel use and post-exposure prophylaxis (PEP). Full text of the ACIP recommendations is in the MMWR 56(41);1080-1084, October 19, 2007.

Hepatitis A is a virus that infects the liver. Infected children may be asymptomatic or have very mild symptoms. Adults are more likely to have symptoms that include fever, abdominal pain, malaise, anorexia and nausea; about 70% will have jaundice. The illness generally lasts several weeks, and most people recover completely. Chronic infection with hepatitis A does not occur. A vaccine to prevent hepatitis A was licensed in 1995, and since then the incidence of reported hepatitis A has declined by 88%¹; however, cases continue to occur both among children and adults, particularly those who travel outside the United States. A total of 34 cases were reported in King County in 2005 and 2006, and 21 (62%) had a history of international travel². Consequently, the need for PEP remains. Transmission of the virus from an infected food handler is another common scenario leading to the need for PEP.

Post-Exposure Prophylaxis for Hepatitis A:

- Age 12 months to 40 years: vaccine is preferred to IG. Administer as soon as possible.
- Age 40 years and older: IG (0.02 mL/kg) is preferred, since information regarding vaccine efficacy is not available and disease is often more serious in adults. However, *vaccine can be used if IG cannot be obtained.*
- Children < 12 months, persons that are immunocompromised, have chronic liver disease, or for whom vaccine is contraindicated: IG (0.02 mL/kg).

- When both IG and vaccine are recommended, they should be given simultaneously. The second dose should be given 6-12 months after the first dose.
- The efficacy of giving IG or vaccine > 2 weeks after exposure has not been established.

Hepatitis A vaccine for Travelers:

- For travelers departing in >4 weeks: Vaccine only
- For travelers departing in <4 weeks: Vaccine [IG (0.02 mL/kg) may be given for optimal protection]
- IG (0.02 mL/kg) only for infants age <12 months, anyone allergic to vaccine components or those that elect not to receive vaccine

¹ MMWR Surveillance Summaries. Surveillance for Acute Viral Hepatitis—United States, 2005. March 16, 2007 / 56(SS03). Page 1.

² Public Health Seattle & King County 2005 Communicable Disease Surveillance Summary. Page 25.

Blast from the Past: Lessons Learned From Last Winter's Windstorm

On December 14, 2006, a powerful windstorm struck the Puget Sound region resulting in widespread power outages. Many King County VFC providers were challenged with safeguarding their vaccine inventory during the extended emergency. Subsequently, 54 clinics reported vaccine losses totaling over \$150,000. Two different surveys were sent to each VFC provider in King County to triage storage incidents and assess providers' capacity to store or move vaccine during a power outage. Response rates were 48% and 47% from the first and second surveys, respectively. The results are reported here.

Forty-seven percent of the total King County VFC Program enrollment reported losing power the day of the storm. Clinics reported an average of 45.2 hours without electricity and most of these clinics moved vaccines to another location. However, vaccine was not accepted by the alternate location 15% of the time. Alternate locations may not have had power (particularly if nearby), or were overwhelmed by storage needs in the community. About one-fourth of clinics surveyed indicated that they need a written agreement with a backup storage site to better prepare for an emergency.

Lesson Learned #1: Have a written backup storage plan in place for emergency power outages.

- See your VFC Provider Manual for an example of an emergency storage plan. Ideally this plan would include a written agreement with one or more backup facilities. Include contact names and phone numbers. The example plan is available as a Word file to make it easier for individual clinics to customize it.

When transferring vaccine, 29% of providers moved refrigerated and frozen vaccine in the same cooler, and refrigerated vaccine was packed with frozen ice packs 86% of the time. It was clear that many providers were unaware that refrigerated vaccine can be damaged when too cold (e.g. if placed in direct contact with ice). Unnecessary losses will result if vaccine freezes during transport. *Refrigerated* cold packs or water bottles can be used for packing *refrigerated* vaccines. Above all, dry ice should never be used to transport refrigerated vaccines. Of the 54 vaccine spoilage incidents, approximately one dozen were due to incorrect storage conditions at the new location (too warm, too cold, refrigerator not plugged in, vaccine misplaced).

Lesson Learned #2: Monitor temperatures carefully. Be aware that freezing temperatures are more damaging to refrigerated vaccine than warmer ones.

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Blast from the Past: Lessons Learned from Last Winter's Windstorm, continued from p. 3

- Pack refrigerated vaccine in a separate cooler from frozen vaccine.
- Allow ice packs to thaw until they sweat before packing *refrigerated* vaccines, or use refrigerated cold packs or water bottles. Dry ice is for frozen vaccines only!
- Pack a thermometer next to the vaccine and monitor temperatures in the new storage location (even if it is a residential refrigerator).
- Whenever possible, use dry ice to pack *frozen* vaccines. Regular ice packs (directly from the freezer) are acceptable if transport time will be 30 minutes or less.
- Ask to assist with or oversee the placement of your vaccines at the back-up location, to assure that they are correctly stored.
- Call the VFC staff following vaccine storage incidents (temperatures outside of the recommended range), including refrigerated vaccine coming into direct contact with ice or freezing temps.

To be better prepared in the future, providers responding to the survey said they needed to have: clear instructions ready and accessible for packing and transporting vaccine during an emergency (23%), adequate packing supplies on hand (21%), and clarity with regard to roles among staff members (10%). Most clinics indicated that they needed a generator to be better prepared for an outage. For clinics that do not have emergency generators the importance of developing an agreement with a backup storage facility is underscored.

Lesson Learned #3: Prepare today for tomorrow's emergency. Anticipate!

- Keep vaccine packing instructions with packing supplies. Include information about proper temperature for transport.

- Packing supplies should include enough coolers to separate refrigerated and frozen vaccine, packing layers (e.g., bubble wrap, foam padding), and thermometers.
- Keep a flashlight in a convenient place in case you are packing in the dark.
- Be sure staff members understand their roles and responsibilities during emergencies. Review your emergency plan in a staff meeting annually, especially before the winter storm season.

Follow-up by VFC staff post-storm found that many providers incorrectly assumed vaccine was spoiled (and some discarded it), before consulting with Public Health.

Lesson Learned #4: Call Public Health if storage temperatures are ever outside of range or were unknown for a period of time.

- Don't assume vaccine is either spoiled or safe to use if temperatures are out of range – please call to discuss the situation. Never discard vaccine unless directed by VFC staff. Spoiled vaccine can usually be returned for an excise tax reimbursement.
- It is not necessary to move vaccines if the power outage is 3 hours or less. If vaccines are not moved, keep the refrigerator or freezer door(s) closed except to check the temperature. As the refrigerator warms up, you can move a few ice packs down from the freezer. Always put the ice packs on the top shelf and move vaccines to lower shelves. **Do not let ice packs touch vaccine directly.**
Note: A correctly packed Styrofoam cooler can store vaccines safely for up to 72 hours.

Thank you, again, to all the providers who made an effort to safeguard their vaccine during the power outage and who participated in the survey.